Remarks/Arguments

Claims 2, 5, 7, 11 and 12 will be pending in this application upon entry of this amendment. Independent claim 10 is replaced with new independent claim 12.

Claims 2, 5, 7, 11 and 10 were rejected under 35 USC 112, first paragraph. Applicant requests reconsideration and withdrawal of this rejection for the reasons that follow.

New claim 12 specifies that the treatment is a curative treatment. Since the amended claim clearly does not include prophylactic treatment, Applicant submits that the stated basis for the rejection is overcome. However, Applicant further asserts that the scope of claim 12 is not different from previously pending claim 10 because claim 10 required the patient to be suffering from pulmonary hypertension. Accordingly, Applicant requests withdrawal of this rejection.

Claims 2, 5, 7, 11 and 10 were rejected under were rejected under 35 USC 103(a) as being unpatentable over Goncharova et al, Tanabe et al, Zimmermann et al, and Dingli et al. Applicants request reconsideration and withdrawal of this rejection for the reasons that follow.

For the reasons stated in the Amendment filed on January 19, 2010, which is here incorporated by reference, Applicant asserts that the cited references do no more than suggest a connection between PDGFR and pulmonary hypertension that at best provides a suggestion to experiment with PDGFR inhibition for the treatment of pulmonary hypertension. Applicant further asserts, for reasons discussed in the above-identified Amendment, that the combined disclosure of the references would not lead the skilled artisan to the present invention, but instead would lead the skilled artisan to experiment with S6K1 inhibitors like rapamycin.

It is clear from the discussion in the Office action that the Examiner is rejecting the claims based on the conclusion that the prior art would make it obvious to try PDGFR inhibitors for the treatment of pulmonary hypertension. However, Applicant asserts that the Examiner is relying on an incorrect legal standard to conclude that the present claims are unpatentable under 35 USC 103.

Appellant's position is supported by the Federal Circuit's opinion in Bayer v. Barr, 575 F.3d 1341; 91 U.S.P.Q.2D 1569 (Fed. Cir. 2009). The Bayer v. Barr opinion at 575 F.3d 1347, discusses when obvious to try is not the proper standard for an obvious rejection:

> In KSR, the Supreme Court stated that an invention may be found obvious if it would have been obvious to a person having ordinary skill to try a course of conduct:

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103.

550 U.S. at 421. This approach is consistent with our methodology in *In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988). See *Procter & Gamble Co. v Teva Pharms. USA, Inc.*, 566 F.3d 989, 996-97 (Fed. Cir. 2009); *In re Kubin*, 561 F.3d 1351, 1359, (Fed. Cir. 2009). *O'Farrell* observed that most inventions that are obvious were also obvious to try, but found two classes where that rule of thumb did not obtain.

> First, an invention would not have been obvious to try when the inventor would have had to try all possibilities in a field unreduced by direction of the prior art. When "what would have been 'obvious to try' would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful" an invention would not have been obvious. *O'Farrell*, 853 F.2d at 903. This is another way to express the KSR prong requiring the field of search to be among a "finite number of identified" solutions. 550 U.S. at 421; see also *Procter & Gamble*, 566 F.3d at 996; *Kubin*, 561 F.3d at 1359. It is also consistent with our interpretation that KSR requires the number of options to be "small or easily traversed." *Ortho-McNeil Pharm., Inc. v. Mylan Labs.*, Inc., 520 F.3d 1358, 1364 (Fed. Cir. 2008).

> Second, an invention is not obvious to try where vague prior art does not guide an inventor toward a particular solution. A finding of obviousness would not obtain where "what was 'obvious to try' was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it." *O'Farrell*, 853 F.2d at 903. This expresses the same idea as the KSR requirement that the identified solutions be "predictable." 550 U.S. at 421; see also *Procter & Gamble*, 566 F.3d at 996-97; *Kubin*, 561 F.3d at 1359-60.

At best, the combined disclosure of the references suggests to explore the general approach of trying PDGFR inhibitors, such as imatinib, to treat pulmonary hypertension. The unpredictability of this general approach is clear from the Examiner's position in the prior rejection under 35 USC 112, first paragraph. None of the cited references contains disclosure that would lead the skilled artisan to reasonably predict that all compounds known to inhibit PDGFR would have utility for treating pulmonary hypertension, and the combined disclosure of the references would not lead the skilled artisan to select imatinib from the potential PDGFR inhibitors. Therefore, Applicant asserts that that even if the presently claimed invention is 'obvious to try', it is nevertheless patentable under the case law discussed in Bayer v. Barr.

For the reasons discussed above, Applicant requests reconsideration and withdrawal of the rejection under 35 USC 112, first paragraph.

Entry of this amendment and reconsideration and allowance of the claims are respectfully requested.

Respectfully submitted,

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Date: 8/4/2010